(1)

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(A)

November 29, 1994

**EXPRESS MAIL- RETURN RECEIPT REQUESTED**

Document Processing Center (TS-790)
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U. S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460

COMPANY SANITIZED

Dear 8(e) Coordinator:

This letter is to inform you of the results of a recently conducted acute oral toxicity study ($LD_{50}$) in rats with a proprietary mixture containing approximately [ ]% $N^1$-(2,4-dichlorophenyl)-N,N-dimethylurea, CAS No. 330-54-1. Groups of 5 male and 5 female Crl:CD®BR rats were fasted overnight and then administered dosages of 1000, 3000, or 5000 mg/kg of the test substance. After dosing, the rats were observed for mortality and clinical signs of toxicity over a 14-day observation period.

Mortalities of 30%, 30%, and 90% were observed in rats dosed at 1000, 3000, and 5000 mg/kg, respectively. Ataxia, limp muscular effects, lethargy, and immobility were observed in rats dosed at 3000 and 5000 mg/kg. The $LD_{50}$ was determined to be 2500 mg/kg.

The clinical signs described above appear to be reportable, based upon EPA guidance regarding the reportability of such data under TSCA Section 8(e) criteria.

Substantiation of our confidentiality claim is enclosed.

Sincerely,

4EHQ-94-13265
4895000055

12/30/94

**Proprietary and Trade Secret Information**
**Confidential Business Information**

## Substantiation of Confidentiality Claim

Information disclosed in this letter and claimed as confidential business information (CBI) is highly confidential. Disclosure of this information to the public or competitors could have substantial adverse economic impact on the submitter's business activities.

Without waiver of rights, submitter herein provides its responses to the nine data issues shown at 40 CFR 2.204(e)(4). Submitter reserves the right to supplement these responses.

(i) Information which is claimed as confidential is described as 'proprietary' or is bracketed.

(ii) Confidential treatment should be afforded for an initial five-year period. Submitter reserves the right to extend this period upon timely notice to the EPA.

(iii) Information is provided voluntarily and only because submitter believes that the test observations meet EPA's reporting criteria as published in the 1991 Reporting Guide. Submission of this information is not an admission that the submitter believes that the information reasonably supports a conclusion of substantial risk to health or the environment. The date of submission is November 4, 1994.

(iv) The business confidentiality claim was made at the time of submission.

(v) To protect unauthorized disclosure, all documents relating to the synthesis and other scientific evaluations of this proprietary mixture are stored in locked, limited-access facilities and designated as proprietary, trade secret, or confidential. Employees having access to the information are contractually prohibited from unauthorized disclosure of their employer's proprietary/confidential information.

(vi) The submitter has not disclosed the claimed confidentiality business information to others.

(vii) There are no other pertinent confidentiality determinations by EPA or other federal Agencies.

(viii) The submitter states that disclosure of the submitted confidential business information would result in harmful effects on submitter's competitive position since the submitter has committed or expects to commit a significant amount of money to research and development of this compound. Disclosure of the CBI information would permit a competitor to specifically know and understand submitter's research efforts with this compound and to forego the necessary time and expense to develop this compound, thus capitalizing on submitter's research and development efforts.

(ix) The information submitted in this notice is voluntarily submitted.

# Triage of 8(e) Submissions

Date sent to triage: APR 0 6 1995

NON-CAP CAP

Submission number: 13265A

TSCA Inventory: Y N D

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Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

| | | | | |
|---|---|---|---|---|
| STOX | CTOX | EPI | RTOX | GTOX |
| STOX/ONCO | CTOX/ONCO | IMMUNO | CYTO | NEUR |

Other (FATE, EXPO, MET, etc.): _____

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Notes:

**THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY**

**For Contractor Use Only**

**entire document:** 0 1 2 **pages** — **pages** 1

**Notes:**

**Contractor reviewer :** LDS **Date:** 1/30/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ-1294-13265 (3) SEQ. A

TYPE: (INT.) SUPP FLWP

SUBMITTER NAME: Confidential

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER/USERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP./USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 11/29/94 OTS DATE: 12/01/94 CSRAD DATE: 12/30/94

CHEMICAL NAME:

CAS#
330-54-1

| INFORMATION TYPE: | | P F C |
|---|---|---|
| 0201 | ONCO (HUMAN) | 01 02 04 |
| 0202 | ONCO (ANIMAL) | 01 02 04 |
| 0203 | CELL TRANS (IN VITRO) | 01 02 04 |
| 0204 | MUTA (IN VITRO) | 01 02 04 |
| 0205 | MUTA (IN VIVO) | 01 02 04 |
| 0206 | REPRO/TERATO (HUMAN) | 01 02 04 |
| 0207 | REPRO/TERATO (ANIMAL) | 01 02 04 |
| 0208 | NEURO (HUMAN) | 01 02 04 |
| (0209) | NEURO (ANIMAL) | 01 02 04 |
| 0210 | ACUTE TOX. (HUMAN) | 01 02 04 |
| 0211 | CHR. TOX. (HUMAN) | 01 02 04 |
| (0212) | ACUTE TOX. (ANIMAL) | 01 02 04 |
| 0213 | SUB ACUTE TOX (ANIMAL) | 01 02 04 |
| 0214 | SUB CHRONIC TOX (ANIMAL) | 01 02 04 |
| 0215 | CHRONIC TOX (ANIMAL) | 01 02 04 |

| INFORMATION TYPE: | | P F C |
|---|---|---|
| 0216 | EPI/CLIN | 01 02 04 |
| 0217 | HUMAN EXPOS (PROD CONTAM) | 01 02 04 |
| 0218 | HUMAN EXPOS (ACCIDENTAL) | 01 02 04 |
| 0219 | HUMAN EXPOS (MONITORING) | 01 02 04 |
| 0220 | ECO/AQUA TOX | 01 02 04 |
| 0221 | ENV. OCCC/REL/FATE | 01 02 04 |
| 0222 | EMER INCI OF ENV CONTAM | 01 02 04 |
| 0223 | RESPONSE REQEST DELAY | 01 02 04 |
| 0224 | PROD/COMP/CHEM ID | 01 02 04 |
| 0225 | REPORTING RATIONALE | 01 02 04 |
| 0226 | CONFIDENTIAL | 01 02 04 |
| 0227 | ALLERG (HUMAN) | 01 02 04 |
| 0228 | ALLERG (ANIMAL) | 01 02 04 |
| 0239 | METAB/PHARMACO (ANIMAL) | 01 02 04 |
| 0240 | METAB/PHARMACO (HUMAN) | 01 02 04 |

| INFORMATION TYPE: | | P F C |
|---|---|---|
| 0241 | IMMUNO (ANIMAL) | 01 02 04 |
| 0242 | IMMUNO (HUMAN) | 01 02 04 |
| 0243 | CHEM/PHYS PROP | 01 02 04 |
| 0244 | CLASTO (IN VITRO) | 01 02 04 |
| 0245 | CLASTO (ANIMAL) | 01 02 04 |
| 0246 | CLASTO (HUMAN) | 01 02 04 |
| 0247 | DNA DAM/REPAIR | 01 02 04 |
| 0248 | PROD/USE/PROC | 01 02 04 |
| 0251 | MSDS | 01 02 04 |
| 0299 | OTHER | 01 02 04 |

TRIAGE DATA: NON-CBI INVENTORY
(YES)
CAS SR NO
[illegible]
[illegible] Non-Cap

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
[illegible]

SPECIES
RAT

TOXICOLOGICAL CONCERN:
(LOW)
MED
HIGH

USE:

PRODUCTION:

-CPSS-

> <ID NUMBER>
8(E)-13265A

> <TOX CONCERN>
L

> <COMMENT>
ACUTE ORAL TOXICITY IN CD RATS IS OF LOW CONCERN. SINGLE ORAL DOSES ADMINISTERED TO GROUPS OF 5 MALE AND 5 FEMALE RATS EACH WERE ASSOCIATED WITH SIGNS OF NEUROTOXICITY AND MORTALITIES AS FOLLOWS: 1000 MG/KG (3/10), 3000 MG/KG (3/10), 5000 MG/KG (9/10). STUDY AUTHORS ASSIGNED AN LD50 AT 2500 MG/KG. FOURTEEN-DAY OBSERVATION YIELDED CLINICAL SIGNS OF POSSIBLE NEUROTOXICITY INCLUDING ATAXIA, LIMP MUSCULAR EFFECTS, LETHARGY AND IMMOBILITY.

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